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Introduction

The Medical Treatment Guidelines review criteria contained herein were developed by the Washington State Medical Association Industrial Insurance Advisory Committee in collaboration with the Office of the Medical Director. These guidelines/review criteria are published by the Department of Labor and Industries as educational tools for providers.

In addition, the guidelines/review criteria are implemented in prospective utilization management programs, the responsibility for which is solely that of the Department of Labor and Industries.

Note: For more copies of the Medical Treatment Guidelines please write to: L&I Warehouse, Department of Labor and Industries, P.O. Box 44843, Olympia, Washington 98504-4843.

Review, Regulate, or Reform?

WHAT WORKS TO CONTROL WORKERS' COMPENSATION MEDICAL COSTS

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WORKERS COMPENSATION RESEARCH INSTITUTE
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Medical Practice Guidelines in Washington Workers' Compensation

Background

The Washington State Medical Association (WSMA) Industrial Insurance Advisory Committee, in conjunction with the Washington State Department of Labor and Industries (L&I), has developed a process for establishing medical practice guidelines. Under authority of WAC 296-20-01001, the WSMA committee advises and assists L&I on issues broadly related to the quality of medical care received by injured workers. Since September 1988, two working subcommittees of the WSMA committee have met on a monthly basis to address 1) medical practice guidelines and 2) issues related to work disability among injured workers. These two subcommittees were established simultaneously because, in the view of WSMA members, injured workers receiving surgery were less likely to recover if disability-related issues were prominent at the time of surgery. Because of the complexity of the disability issue, the work of these two subcommittees has been difficult to merge. Nonetheless, the most recent guidelines (e.g. lumbar fusion) have incorporated disability related issues.

The need to establish practice guidelines was recognized by the members of the Washington State Medical Association committee in 1988, when the inpatient utilization review (UR) program was established. This program provides preadmission medical necessity review for inpatient admissions, particularly related to surgical procedures. Earlier in 1988 L&I had established and published admission criteria for the inpatient medical treatment of back pain (for those that did not require surgery). Within one year of publishing these criteria, medical back admissions for the department fell by 60 percent. Surprisingly, a statewide sentinel effect was also seen in hospital discharge data. The inpatient UR program was originally contracted to an out-of-state vendor who used proprietary surgical criteria to establish medical necessity. Although these criteria are used nationally by insurance companies, they were felt to be inadequate in detail and specificity for L&I's purpose of assuring quality.

The first WSMA medical guidelines subcommittee meeting occurred in September 1988, in response to an L&I request to assist with development of guidelines for lumbar fusion. After three to four months of meetings, the subcommittee, which included several prominent spine surgeons from the Seattle area, presented a draft of guidelines for fusion to the full WSMA committee. In 1989, L&I published the fusion guidelines.

Since the publication of the medical back and fusion guidelines, 11 other guidelines have been established and published (Table 1). Although most have been guidelines for surgery, one recently developed guideline is for use of scheduled drugs for non-malignant pain. Another guideline, related to causality and treatment of carpal tunnel syndrome, has just been published.

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¹This work was done in full collaboration with the Washington State Medical Association Industrial Insurance Advisory Committee.

The WSMA/L&I Medical Practice Guideline Process

The process used by the WSMA medical guidelines subcommittee is a combination of scientific evidence and community-based expert opinion. Although the consensus process is relatively informal, most aspects of the process for each guideline have been quite consistent, employing the following steps.

- Prioritization of guidelines
- Consensus development
- Formatting a decision-making algorithm
- Implementation
- Evaluation

Table 1. WSMA Practice Guidelines for Washington Workers' Compensation

| Guideline | Date Published |
|-------------------------|----------------|
| Medical back admissions | 1988 |
| Lumbar arthrodesis | 1989 |
| Lumbar laminectomy | 1990 |
| Thoracic outlet release | 1990 |
| Cervical laminectomy | 1991 |
| Knee surgery | 1991 |
| Shoulder surgery | 1991 |
| Ankle/foot surgery | 1992 |
| Scheduled drug use | 1992* |
| Lumbar arthrodesis | 1994 |
| Lumbar MRI | 1994 |
| Shoulder MRI | 1994 |
| Carpal tunnel surgery | 1994 |
| * WSMA Bulletin | |

PRIORITIZATION OF GUIDELINES

For the most part, prioritization has depended on 1) frequency of the problem, 2) cost, 3) poor outcomes or, 4) weak biologic plausibility. The lumbar fusion guideline, for example, was addressed first since no proprietary criteria for fusion were available. Other surgical guidelines were addressed because they are frequently performed (e.g., back, neck and knee). Both lumbar fusion and thoracic outlet surgery are relatively infrequent, but neither has strong clinical trial support nor clear biologic plausibility.

CONSENSUS DEVELOPMENT

Consensus development has generally taken place between the permanent members of the subcommittee (orthopedic surgeon, physiatrist, occupational medicine physician, neurologist, neurosurgeon) and *ad hoc* invited physicians who are clinical experts in the topic to be addressed. One hallmark of these discussions is that since few of the guidelines being discussed have a scientific basis, disagreement on specific points is common. Following the initial meeting on each guideline, subsequent meetings are only attended by permanent members unless information gathering from invited physicians is complete.

In order to reach consensus, the following assumptions are made.

- 1. The (surgical) guideline is meant to increase the proportion of surgical requests authorized for workers who truly require surgery, and to decrease the proportion of such authorizations among workers who do not fall within the consensus guideline.
- 2. The guideline is meant to be a gold standard for the majority of requests, but for the minority of workers who appear to fall outside of the guideline and whose complexity of clinical findings exceeds the specificity of the guideline, a further review by a specialty-matched physician is conducted.
- 3. The guideline is further refined after input from other community-based practicing physicians.
- 4. The guideline is evaluated to determine if it is having a beneficial effect.
- 5. The guideline-setting process will be iterative, that is, although initial guidelines may be quite liberally constructed, subsequent tightening of the guideline would occur as other national guidelines are set, or other scientific evidence (e.g., from outcomes research) becomes available.

Assumption number two is particularly important and warrants elaboration. The intention of the WSMA Medical Guidelines Subcommittee was to develop treatment guidelines that would be implemented in a nonadversarial way. The subcommittee tried to distinguish between clear-cut indications for procedures and indications that were questionable. The expectation was that when surgery was requested for a patient with clear-cut indications, the request would be approved by nurse consultants. However, if such clear-cut indications were not present, the request would not be automatically

denied. Instead, it would be referred to a physician consultant who would review the patient's file, discuss the case with the requesting surgeon, and make recommendations to the claims manager. The flexibility built into this decision making process was important in two ways. First, it enabled the subcommittee to develop surgical indications fairly quickly, since the members were aware that the indications would not be applied in a heavy-handed way. Second, it played a major role in legitimizing the work of the subcommittee in the eyes of practicing physicians in Washington.

FORMATTING A DECISION MAKING ALGORITHM

Once the principles of the guideline are reached by consensus, these principles are placed in a format consisting of and/or statements intended to aid professional nurse reviewers in deciding whether a particular surgical request falls within the guideline. (See lumbar laminectomy example, Appendix A).

IMPLEMENTATION

Most guideline development efforts, particularly at the federal level, stress dissemination of guidelines and hoped for change in physician behavior. The Institute of Medicine's report on development of practice guidelines (1992) differentiated between guidelines (intended for practitioners) and medical review criteria (intended to assess care).

It has become clear that, without a method of implementation, medical practice guidelines may be inconsistently and informally applied. Most of the surgical guidelines established by WSMA have been implemented in the context of the inpatient UR program. It has been critical in contract negotiations with UR vendors to specify that the vendor is willing to substitute WSMA-generated guidelines for less specific standards already in use by the company. More recently, the Department of Labor and Industries initiated an outpatient UR program, and this has allowed full implementation of guidelines related to outpatient procedures (e.g., carpal tunnel surgery, MRIs).

EVALUATION

The Department is developing a database sufficient to provide continuous evaluation of all newly implemented guidelines. Current evaluation efforts, dependent on retrospective vendor reports, are labor intensive and are not responsive enough to emerging needs. The new database could identify both provider indicators of outlying behavior, as well as worker-based health outcomes (e.g., time loss duration post surgery).

The Relationship of the WSMA/L&I Medical Practice Guideline Process to National and Statewide Guideline Efforts

Three specific types of guidelines may be differentiated. The first, a *point of service guideline*, is one which is used to determine if a specific medical intervention is

warranted at a given point in time. Most of L&I's surgical guidelines would fall in this category. A second variety of guidelines is one which would be used to follow a patient over time, the guideline perhaps containing a number of red flags to indicate the risk for an adverse outcome. Such a guideline could be called a *longitudinal guideline*, one which helps in prospectively following patients. The forthcoming guideline for treating low back pain from the Agency for Health Care Policy and Research is an example. L&I's new guideline for use of scheduled drugs for nonmalignant pain would also fall in this category. A third type of guideline would relate to criteria for use of new technologies. Similar *technology evaluation guidelines* have been developed by the National Blue Cross/Blue Shield Association (Table 2), and would be more likely related to system-wide approaches to payment for new technologies whose efficacy is not clearly demonstrated. Technologies with proven efficacy would be dealt with as a point of service guideline.

Table 2. Blue Cross/Blue Shield National Association Technology Evaluation Criteria*

| 1. | The Scientific evidence must permit conclusions concerning the effect of the |
|------------|--|
| | technology on health outcomes. |
| 2. | The technology must improve net health outcome. |
| 3. | The technology must be as beneficial as any established alternatives. |
| 4. | The improvement must be attainable outside the investigational setting. |
| 5 . | The technology must have final approval from the appropriate government |
| | regulatory bodies. |

* Technologies must meet all five criteria to be recommended for coverage.

Woolf (1992) outlines four common approaches for developing practice guidelines that range from relatively unstructured, informal methods to very formal, structured approaches. Woolf characterizes the approaches as:

- 1. Informal consensus development, the most common approach, consists of a simple literature review and an unstructured consensus process.
- 2. Formal consensus development uses a structured approach to assess expert opinion and to reach agreement on recommendations.
- 3. Evidence-base guideline development bases recommendations directly on scientific evidence, and research findings are stressed over expert opinion.
- 4. Explicit guideline development is based on analyzing the potential benefits, harms, and costs of available interventions, estimating the possibility of the outcomes, and comparing the desirability of the outcomes based on patient preferences.

NATIONAL DEVELOPMENTS

The New England Medical Centers Institute for the Improvement of Medical Care and Health recently conducted a survey of eight prominent organizations that have

innovative guideline development programs, (Audet, 1990). The organizations surveyed all have systematic approaches to guideline development and illustrate the spectrum of approaches described by Woolf. The various approaches provide a good point of reference for evaluating L&I's guideline development efforts.

Goals of guideline development. The goals of guideline development are fairly common across the organizations surveyed. All eight programs indicate that the goal of their program is to improve the quality and effectiveness of care. Six of the eight organizations surveyed stated that cost control is a secondary reason for developing guidelines.

Methods for developing practice guidelines. Guideline development methods vary considerably in terms of the approaches to reviewing current evidence, the use of national versus local experts, and consensus development methods.

Review of Current Evidence. The Harvard Community Health Plan, a leading HMO, relies on comparatively informal methods. The leader of a guideline effort conducts an informal literature review and distributes key papers to a consensus group. This method is similar to the approach used by L&I and is characterized by Woolf as *informal consensus*. In contrast, RAND and Value Health Sciences conduct an exhaustive review of the literature. The American College of Physicians uses an even more formal review process where experts are selected to summarize the literature in scholarly background papers. The papers include a description of methods used to analyze the background data from the literature.

Experts and Consensus Development. The Harvard Community Health Plan employs a nominal group process followed by a Delphi procedure which draws on local physicians who are likely users of the guidelines.

This is comparable to the approach used by L&I, although L&I involves fewer end-users. RAND and Value Health Sciences convene a group of nationally known experts who apply a rating system to the findings from extensive literature reviews, followed by a Delphi procedure. The American College of Physicians develops position papers which undergo review by all appropriate specialty societies.

Guideline Implementation. All eight organizations surveyed acknowledged they pay more attention to guideline development than they do to guideline implementation. Harvard Community Health Plan, Value Health Sciences, and MetroHealth employ computer software combined with monitoring and training programs to promote use of guidelines. In comparison, the American College of Physicians and the American Medical Association have no implementation strategy other than the dissemination of the guideline. L&I's application of guidelines varies; although most guidelines are rigorously applied through utilization review programs, the scheduled drug use guideline has been widely disseminated by WSMA and used internally, but has not been formally implemented in a UR program.

Evaluation Research. Most organizations surveyed conceded that they devote the bulk of their resources to guideline development and commit few resources to

evaluating guideline impacts. However, Harvard Community Health Plan is conducting a controlled study to evaluate the impacts of some of its guidelines. MetroHealth is also conducting a similar study. Value Health Sciences conducts hospital chart audits to determine the effectiveness of their preadmission review programs. However, evaluation efforts are considered relatively undeveloped by the survey authors. L&I's emphasis on evaluation puts the agency in a leading position relative to other model programs.

Summary. There is an apparent consensus on the goals of guideline development among the organizations surveyed, namely, to improve the quality of care and control costs. However, there is a spectrum of approaches to guideline development which vary from the relatively informal methods used by the Harvard Community Health Plan to the highly structured methods used by RAND, Value Health Sciences and the American College of Physicians. L&I's method tends to fall on the informal end of the spectrum and is most like the approach used by the Harvard Community Health Plan. However, this program is somewhat more developed than L&I's and may be a useful reference point for program enhancements. HCHP has been cited as a model program by Group Health Cooperative of Puget Sound.

Details of the Harvard Community Health Plan. The Harvard Community Health Plan (HCHP) is a 400,000 member HMO in Massachusetts. In 1986 it began what is now considered to be a prototype approach to developing practice standards. (Gottlieb, 1990) The program focuses on developing clinical algorithms for health problems that are commonly encountered by the HMO's practicing physicians. The algorithms outline a step-wise process for diagnosing and treating common health problems. The basis of the guideline formation process is to combine pertinent evidence from the medical literature, expert consultants, and HCHP practitioners to generate consensus algorithms.

HCHP initially developed a CME workshop to introduce practitioners to the program and encourage their involvement in algorithm development. Early concerns about *cookbook medicine* and worries about a top-down approach to developing and applying standards were addressed through open communication in the workshops. This apparently led to building support for the program among practicing physicians. A hallmark of both the HCHP and L&I programs is reliance on practicing clinicians to develop guidelines.

The program has completed and distributed 31 guidelines and has 50 ore underway. More than 300 physicians have been involved in the process. As the program has evolved, criteria have been developed for selecting topics for guideline development (Table 3). In addition, the program has outlined a thoughtful process for developing guidelines (Table 4). The program is also experimenting with innovative education and training methods for implementing guidelines.

LOCAL DEVELOPMENTS IN WASHINGTON STATE

Group Health Cooperative of Puget Sound is currently developing a clinical guidelines program. They are looking at the HCHP guidelines program for direction. The First Choice Health Network is using automated guidelines known as *Patterns of Treatment* which were developed by Don Herrington, MD, of California. Another insurer in the state is also using this software. First Choice Network indicates that their initial attempts at sharing the comparative statistics produced by the software has been well received by their physicians. Furthermore, physicians appear to be using the profiles to evaluate their practice patterns in relation to their peers.

Table 3. Criteria for Choosing Clinical Algorithm Topics

- Common clinical conditions
- Unexplained variation in clinical practice (perceived or documented)
- Unexplained variation in utilization of limited or costly resources
- General clinical uncertainty or controversy
- Uncertain indications for risky or costly intervention
- Internal resource access or supply constraints
- Apparent risk management problem
- Introduction of new diagnostic test, therapeutic procedure or medication
- Quality of care problem perceived by patients, clinicians or managers

SOURCE: Audet, 1990

The 1990 Study of State Purchased Health Care recommended that the state establish a medical directorship that will work with local practitioners to establish practice standards. The study also recommended that state agencies develop methods to evaluate provider compliance with the standards and to provide feedback to practitioners. These recommendations were superseded by the Washington Health Services Act of 1993, which authorized the new Health Services Commission and the Department of Health to promulgate rules in relationship to practice *indicators*, and that such *indicators* be based on the best available scientific evidence and consensus expert opinion.

Table 4. The Algorithm Development Process at HCHP

Project Planning

- 1. Identification of topic
- 2. Identification of intended users
- 3. Determination of suitability for *local* or *central* consensus
- 4. Identification and selection of group leader
- 5. Identification and selection of members of consensus group

Consensus Algorithm Development

- 6. Literature search and summary
- 7. *Seed algorithm* construction
- 8. Review of literature and seed algorithm by consensus group members
- 9. Brief algorithm and consensus development training
- 10. Consensus development via nominal group process and/or Delphi method

Algorithm Review

- 11. Identification of *essential nodes* for possible measurement
- 12. Identification and selection of algorithm keeper
- 13. Selection of date for next review and revision
- 14. Review and approval of algorithm

Implementation

- 15. Distribution of algorithm with request for feedback
- 16. Design of implementation strategies

SOURCE: Audet, 1990

Impact of the WSMA/L&I Medical Practice Guidelines

Plans are currently in place to evaluate the impact of the guidelines, and the Department has done a preliminary analysis of the impact of the original lumbar fusion guidelines. A 10-month experience in 1989 was reviewed. During this time, approximately 17 percent of requests for lumbar fusion were denied. Moreover, the workers in this group experienced claim resolution in the subsequent two years significantly more frequently (36%) than those who had fusion surgery (22%, p< 0.05). A more recent preliminary analysis of the fusion experience in 1991 revealed that the guideline had an initial significant effect but that this effect has only marginally increased with time. The implication was that a more specific standard would be in order at this time, and that any sentinel effect of inter-physician education had already been maximized.

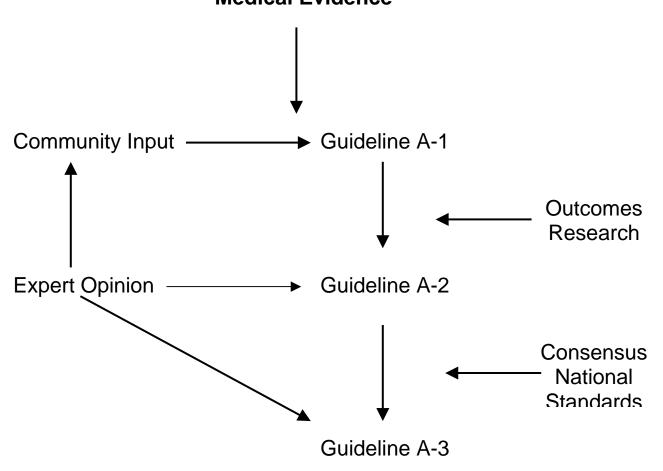
Relationship to Outcomes Research

The guideline setting process should be iterative in nature, with increasingly specific guidelines produced as more scientific evidence becomes available (Figure 1). The Occupational Epidemiology and Health Outcomes program at the University of Washington, funded by Accident and Medical Aid fund monies, conducts outcomes research related to the L&I guidelines process. Outcome studies related to carpal tunnel surgery (Adams, 1994), lumbar fusion (Franklin, Haug, 1994), and thoracic outlet (Adams, 1994), lumbar fusion (Franklin, Haug, 1994), and thoracic outlet surgery (Franklin, Fulton-Kehoe, 1994), have been completed and have led to substantial changes in previously published guidelines. The principal example is the newly published guideline on lumbar fusion (Page 32), the most specific such guideline currently available. A new guideline on thoracic outlet surgery, not yet published, will require objective neurologic loss prior to approval of such surgery.

This iterative process stands in contrast to the method in some states of placing guidelines in regulation. Although such regulation could aid in the dissemination and quality oversight of guidelines, flexibility in creating updated guidelines might be limited.

Figure 1 WSMA/DLI Iterative Process for Setting Medical Guidelines

Medical Evidence



Vertical line: Increasing probability that guidelines will improve the quality and outcome of medical care.

Legal Implications of the Guideline Process

Two principal legal questions have been addressed in regard to guideline development:

- 1. Are the physicians participating in the WSMA/L&I guideline development process protected from tort action?
- 2. Are practicing physicians who adhere to such guidelines protected from tort action?

In regard to question 1, an assistant attorney general's informal opinion in 1989 was that any physician participating on a voluntary (non-pay) basis in a medical committee established in RCW/WAC for quality assurance purposes would be defended by the full legal resources of the state. The principal successful action taken in the past against physicians participating in quality assurance decisions utilized federal antitrust law (Patrick decision, Oregon, 1986); however subsequent federal and state legislation protects physicians against similar use of federal antitrust law. (Curran, 1989)

Little precedent exists in regard to question 2. The state of Maine has passed a statute protecting physicians who utilize guidelines established by their peers. (Main statutes, 1989-91) This statute provides an affirmative defense for physicians in malpractice situations, who were complying with their specialty's guidelines. It is likely that similar statutory protection will occur as part of health care reform efforts in other states.

An additional legal issue relates to the weight of WSMA opinion at the Board of Industrial Insurance Appeals. If an individual request for surgery does not meet WSMA's guidelines, and is rejected by L&I, it is theoretically possible that such denial of surgery could be overturned at the Board. This fundamental tension between the authority of L&I to implement WSMA community-based treatment guidelines, and the individual workers' or provider's right to appeal such decisions to the Board, will need to be resolved if guideline use in the context of worker's compensation is to be a successful effort. A related underlying assumption of the WSMA guideline process has been that specific indications for surgery ought to be biologic and not based in the adversarial relationships classically engendered in worker's compensation.

Technology Assessment

The assessment of the efficacy of emerging technologies has proved particularly vexing for L&I and other state agencies. The principal problem lies in a dual standard for approval of drugs and new devices at the FDA. Drugs must be proven to be both safe and effective when they are approved for use. New devices, on the other hand, may receive "premarket approval" based on much less stringent safety and efficacy data. Although the intent of this dual standard was to foster development of new technologies, the real effect is that relatively untested devices may gain credibility within the medical community. The Safe Medical Devices Act of 1990 (PL101-629) (DHHS FDA, 1991) gives the FDA more authority to monitor the use of premarket approved devices. For example, hospitals may now be audited for adverse events related to devise use. Nonetheless, the responsibility for reimbursement for what are essentially

investigational devices is left to third party payers. Criteria similar to those used by the Blue Cross/Blue Shield National Association (Table 2) or criteria based on improvement in net health outcome could help reconcile the worker's compensation "palliative vs. curative care" issues.

The relationship of the WSMA guideline work to Board of Industrial Insurance Appeals activity is particularly critical in the technology area. One example is use of the epidural (spinal) stimulator to treat chronic low back and leg pain. On three separate occasions between November 1990 and June 1991, the WSMA Industrial Insurance Committee reviewed safety and efficacy data on this device and voted unanimously to urge L&I not to authorize its use in any case. At least 3 cases appealing the nonauthorization have appeared before the Board, all of which have been upheld in the Department's favor. However, two of the cases were reversed at Superior Court. Although these higher court decisions are not precedent setting, L&I is working to create new regulations that would strengthen the amount of scientific evidence that would be required to justify coverage of emerging procedures and diagnostic tests. Such regulations could further clarify the authority of the WSMA guidelines committee.

A final example of the new technology dilemma facing L&I is the use of pedicle screw fixation devices by orthopedic surgeons to assist in achieving solid lumbar fusion. Most of the fixation devices in use today are not approved for use by the FDA, and research at the University of Washington has suggested adverse outcomes from their use. (Franklin, Haug, 1994) Nonetheless, nearly one-half of all fusion patients have received this device as an adjunct to lumbar fusion surgery. The new fusion guideline (Page 32) contains specific language that must be incorporated into informed consent that explicitly states the experimental nature of these devices.

Future Research and Recommendations

The hallmarks of the WSMA/L&I process for setting medical guidelines are that it is 1) driven by community-based expert opinion, 2) designed to be responsive to end users (physicians, L&I), 3) primarily based (implemented) in prospective review programs and 4) flexible enough to be iterative in nature. The iterative nature of the process is crucial in allowing for continuous improvement of guidelines based on emerging scientific evidence and national consensus efforts (Figure 1). Building on these strengths, the following recommendations should be considered:

 The WSMA/L&I guideline process has been endorsed by a formal labor-management consensus process, the statutory Workers Compensation Advisory Committee.
 Similar endorsement in other states could improve understanding of the value of practice guidelines in workers compensation.

- Enhancements to the current process should include:
 - Development of methodologies to maximize community-based physician input and support
 - Expansion of the capacity of L&I prospective review programs to implement longitudinal guidelines.
 - Better coordination of case management of injured workers whose care does not fall within established medical guidelines.
 - Formalization of criteria for prioritizing guidelines to meet both short and long term needs.
 - Better design of internal evaluation procedures to determine if guidelines are improving net health outcomes.
- In order to maximize limited resources, increased networking, demonstration projects and sharing of expertise should be pursued with other state and federal agencies and professional societies which are involved in the guideline development and technology assessment processes.
- The relationship of the WSMA/L&I guideline process to existing or emerging guidelines should be clarified in policy. To the extent possible in the future, guidelines in use by utilization management vendors should be available for review by the WSMA medical guidelines committee. In most cases, a WSMA/L&I guideline should be used rather than more generic or nonspecific guidelines already in use by the vendor. If a guideline is established by a nationally recognized group (e.g., RAND Corporation, Agency for Health Care Policy and Research) that a) exceeds the specificity of a WSMA/L&I guideline, b) is more clearly based on stronger scientific evidence, c) has broader consensus, and d) is implementable, then such a guideline could replace an existing WSMA/L&I guideline. However, even in this case, acceptance by the WSMA medical guidelines committee would be critical.
- For new technologies which have received premarket approval by the FDA, but whose efficacy data is unclear, the following requirements for requesting physicians are recommended:
 - Physicians should have Institutional Review Board approval from their own institution (e.g., hospital, HMO) to perform the procedure
 - The physician should be part of a formal data collection effort
 - The physician should supply data to L&I and the WSMA medical guidelines committee sufficient to meet the Blue Cross/Blue Shield criteria for technology assessment.

For those technologies which **do not** have FDA approval, but which are in use in the community, the above criteria should apply and L&I should require that appropriate informed consent language be included in guidelines (see Page 33, Lumbar Fusion Guidelines).

 The WSMA medical guidelines committee should strive to include principles of disability prevention and management in their guideline process.

- The interface between the WSMA/L&I guideline process and the role of the Board of Industrial Insurance Appeals should be clarified, perhaps in statute. At a minimum, medical expertise resident on the board could help clarify disputes in regard to use of community-based medical guidelines. The key issue here is not whether or not the WSMA Industrial Insurance Advisory Committee has the authority to establish medical guidelines for L&I, but rather whether the facts of the worker's case were properly interpreted within the context of the guideline.
- Clear definition of key terms should be made in WAC and policy. For WAC these could include clearer definition of *experimental*, new *technology*, and *net health* benefit. In policy, this could include *guidelines*, *standards*, and other key terms.
- L&I should, along with other state agencies, develop a strategic plan to a) enhance legal protection for peer reviewers and b) allow compliance with state mandated guidelines to be an affirmative defense in malpractice situations.
- The capacity of the University of Washington and L&I to conduct outcomes research on worker's compensation specific health issues should be enhanced.

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